DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 23, 2014

NEWCLIP TECHNICS
% Mr. J.D. Webb
Official Correspondent
The OrthoMedix Group, Incorporated
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K142502
Trade/Device Name: Alians Ulna Locking Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: October 3, 2014
Received: October 6, 2014

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K142502

Device Name

ALIANS ULNA LOCKING PLATING SYSTEM

Indications for Use *(Describe)*

The Alians Ulna Locking Plating System is intended for ulnar shortening osteotomy.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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4. 510 (k) Summary for the Alians Ulna Locking Plating System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following 510(k) summary is submitted for the Alians Ulna Locking Plating System.

Summary preparation date: July 17, 2014

1. Submitter:

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Contact Person:

J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

2. Trade name: Alians Ulna Locking Plating System

Common Name: Plates for ulna shortening osteotomy
Screws associated

Product code: HRS/HWC

Classification Name: Plate, Fixation, Bone
(21 CFR part. 888.3030)
Screw, Fixation, Bone
(21 CFR part. 888.3040)

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3. Predicate or legally marketed devices which are substantially equivalent:

- The Synthes One-Third Tubular DCL Plate (K011335).
- Newclip Radius Plates (K061917)
- Newclip Clavicle Plate System (K100944)
- Newclip Distal Radius Plate (K130774)

4. Description of the device:

The Alians Ulna Locking Plating system consists of a plate with many screws as holes (slots) designed for ulnar shortening osteotomy. The plates and screws are manufactured from titanium alloy and color anodized.

The Alians Ulna Locking Plating system will be provided non-sterile for sterilization by health care professional's prior use.

Materials:

Titanium alloy Ti-6Al-4V ELI (conform to ASTM F 136-12a and/or ISO 5832-3).

Function:

The implants of the Alians Ulna Locking Plating System are indicated for fixation of ulnar shortening osteotomy.

5. Substantial equivalence claimed to predicate devices:

The Alians Ulna Locking Plating System is substantially equivalent to Synthes One-Third Tubular DCL Plate (K011335), to the Newclip Radius Plates (K061917), to the Newclip Clavicle Plate System (K100944) and to the Newclip Distal Radius Plate (K130774) in terms of intended use, design, materials used, mechanical safety and/or performance.

6. Intended use:

The Alians Ulna Locking Plating System is indicated for ulnar shortening osteotomy.

7. Non-clinical Test Summary:

The following tests were conducted:

- Comparative fatigue compression tests on plates.
- Comparative static tests on plates.
- Pullout and torsional strength tests on screws.

8. Clinical Test Summary:

No clinical studies were performed.

9. Conclusions Non-clinical and Clinical:

The Alians Ulna Locking Plating System is substantially equivalent to the predicate devices in terms of indications for use, design, material, and function.